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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,707	07/06/2001	Roger E. Darois	D0188/7126	4890

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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09/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/900,707

Applicant(s)

DAROIS ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/07 has been entered.

Information Disclosure Statement

The listing of references in the Remarks (Woodward and Boyers) is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: each article or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Remarks have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing

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the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The amendment filed 6/19/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "The adhesion resistant properties of an implantable soft tissue repair prosthesis are affected by various factors, such as the surface texture and the porosity of the material that forms the prosthesis or portions of the prosthesis. A prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon its particular structural characteristics. In one embodiment, the barrier **24** has a surface texture and a porosity that are each less than 10µm to inhibit the formation of adhesions thereto."

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "The barrier layer having a surface texture and a porosity less than 10 μ m" such that this inhibits adhesions was not described in the specification to define a material property that results in this effect. The disclosure lists materials that prevent adhesions. Thus, one of ordinary skill in the art would assume that if the same materials are found in the prior art they must possess the same properties. The disclosure provides no definitions of porosity or any surface texture to provide a basis to compare materials. Thus, the claims contain new matter.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 46,47,50,54-56,59-62,65-68,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. (5695525) in view of Pease (2671444). Mulhauser shows (Figs. 4a,4b) a surgical repair material comprising a fabric **34**, a barrier layer **36** and an edge barrier **32**. Mulhauser additionally illustrates in Figs. 2a,2b,3h the frame structure located at the edge to form an edge barrier. Regarding claims 50,56,62,68, Mulhauser discloses the fabric mesh can be polypropylene, col. 4, lines 37-40. Mulhauser additionally discloses the mesh fabric and barrier layer can be joined by sewing or stitches, col. 5, lines 48,49. Mulhauser discloses that the frame or edge barrier is solid or rigid to provide support to the fabric (col. 4, lines 22,23) and thus

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would inhibit adhesions from forming. However, Mulhauser et al. fail to explicitly disclose the "edger barrier" to have a surface texture that results in preventing adhesions. Pease teaches (Figs. 1,3) to have an "edge barrier" 16 to reduce adhesions. Pease also teaches the treatment of the material or polymer to create an inert or adhesion resistant material, col. 3, lines 33-39,57-60. It would have been obvious to one of ordinary skill in the art to use the teaching of Pease to provide the tissue edge or contact area with adhesion resistant properties in the prosthetic repair device of Mulhauser et al. such that it does not cause any inflammation or discomfort to the patient that would result from adhesions. It would have been an obvious matter of design choice to modify the porosity of the material, since applicant has not disclosed that using the less than 10µm porosity provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the material taught by Mulhauser or the claimed less than 10µm porosity material in claim(s) 46,53,59,65, because both edge barriers perform the same function of preventing material from adhering thereto.

Claims 53,56,65,68,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier (3416524) in view of Pease (2671444). Meier shows (Fig. 2) a surgical repair material comprising a fabric 15, a barrier layer 14 and an edge barrier 12. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Regarding claims 56,68, Meier discloses the fabric layer can be polypropylene, col. 2, lines 1-5. Fig. 1 clearly shows a mesh

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structure. Meier discloses the edge barrier is made of an inert material and thus would inhibit the formation of adhesions. However, Meier fails to disclose the material has a porosity less than 10 μ m and surface texture to result in preventing adhesions. Pease is explained supra. It would have been obvious to one of ordinary skill in the art to use the teaching of Pease to provide the tissue edge or contact area with adhesion resistant properties in the prosthetic repair device of Meier such that it does not cause any inflammation or discomfort to the patient that would result from adhesions. It would have been an obvious matter of design choice to modify the porosity of the material, since applicant has not disclosed that using the less than 10 μ m porosity provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the material taught by Meier or the claimed less than 10 μ m porosity material in claim(s) 53,65, because both edge barriers perform the same function of preventing material from adhering thereto.

Claims 48,49,51,52,57,58,63,64,69,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser et al. '525 in view of Pease '444 as applied to claims 46,47,56,62,68 above, and further in view of Gianturco (5258000). Mulhauser in view of Pease is explained supra. However, Mulhauser as modified by Pease fails to disclose the stitching pattern about the outer peripheral edge or that the barrier material is PTFE. Gianturco teaches that peripheral edge stitching is done to strengthen the repair device, col. 5, lines 20-22. Gianturco also teaches that PTFE is used because it prevents tissue ingrowth used in repairing sensitive tissue and organs, col. 5, lines 27-

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32. It would have been obvious to one of ordinary skill in the art to incorporate stitches at the peripheral edges for greater support of the repair material and use PTFE for its inhibition of tissue adhesion as taught by Gianturco with the repair device of Mulhauser as modified by Pease such that it improves the strength of the tissue in the weakened area of repair.

Response to Arguments

Applicant's arguments with respect to claims 46,53,59,65 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments focus on the prior art failed to disclose any suggestion of the material having the property of reduced adherence to tissues. These arguments are moot with respect to the new grounds of rejection. Regarding the porosity, it is within one of ordinary skill in the art capability to provide a surface texture and porosity that has the desirable property of reduced adhesion since the general conditions of a claim are disclosed in the prior art, discovering the optimum characteristics involves only routine skill in the art. Regarding the comments about the articles mentioned in a prior response to disclose surface characteristics, first the Examiner would like to remind Applicant that if they want these references to be properly considered then they should be submitted in a 1449 form. Secondly, the references discuss surface irregularities in the materials that permit adhesions. Nowhere in the references of Mulhauser or Meier do the authors discuss that there is any surface irregularities in the material of the "edge barrier". Thus, Applicant has provided no evidence that these patents disclose a material with surface

irregularities or have had the material tested to prove that. However, the new art applied above in the current office action teaches a reduction in surface irregularities to eliminate adhesions from attaching to the material and meets the new limitation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

